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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,711	02/22/2002	Ramanan Ramaswami	Ramaswami-1	1247

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EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/081,711	Applicant(s) RAMASWAMI ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, and 7 rejected under 35 U.S.C. 102(b) as being anticipated by Kwiatek et al (USPN 4,573,996). The claims are drawn to a device comprising a vasodilating agent and a carrier, where the carrier is methylcellulose, and the vasodilating agent is nitroglycerine.

Kwiatek et al teaches a device which topically delivers vasodilating agents. The device comprises methylcellulose as a carrier, and discloses the vasodilating agent to be nitroglycerine (col. 10, lin. 39 – 50; Example 1; claims 16, 22 – 25). These disclosures render the claims anticipated.

3. Claims 1- 3, 5, and 7 rejected under 35 U.S.C. 102(b) as being anticipated by Kigasawa et al (USPN 4,695,465). The claims are drawn to a device comprising a vasodilating agent and a carrier where the vasodilating agent is selected from the group consisting of nitroglycerine, verapamil, diltiazem, and nifedipine. The carrier is recited to be methylcellulose.

Kigasawa et al teaches a soft patch device which delivers vasodilating agents including nitroglycerine, verapamil, diltiazem, and nifedipine (col. 2, lin. 35 – 45). The carrier for the device is recited to be methylcellulose (col. 4, lin. 63 – 68). These disclosures along with other render the claims anticipated.

4. Claims 1 – 3, 7, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Sparks et al (USPN 4,952,402). The claims are drawn to a device that delivers vasodilating agents along with a carrier. The carrier is methylcellulose and biodegradable. The agent is selected from vasodilators well known in the art.

Sparks et al discloses a controlled release formulation comprising vasodilating agents and carrier. The formulation is made into a delivery device where the vasodilating agents are selected diltiazem, and nifedipine, and the carrier can be biodegradable, and be selected from biodegradable polymers such as polyurethane (col. 3, lin. 40 – col. 4, lin. 10; col. 5, lin. 25 – 35). These disclosures render the claimed invention anticipated.

5. Claims 1 – 3, 5, 12 – 15, 17 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Medford et al (USPN 5,380,747). Claims 1 – 3, 5, and 12 are drawn to a device that delivers vasodilating agents and comprises a carrier. The vasodilating agents are selected from the group of compounds well known in the art. The carrier is recited as biodegradable. Claims 13 – 15, 17 and 23 are drawn to method of providing vasodilating to a selected site in a patient, using the device of the invention.

Medford et al teaches a treatment for cardiovascular tissues, where a device comprising a carrier and a vasodilating agent is applied to tissue in need (col. 4, lin., 33 – 45). The agents are discloses as calcium channel blockers such as verapamil, diltiazem, and nifedipine (col. 4, lin. 55 – 60; col. 15, lin. 45 – 53; col. 16, lin. 18 – 21). The carrier for the device is disclosed as a biodegradable polymer. These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1 – 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kwiatek et al (USPN 4,573,996), Kigasawa et al (USPN 4,695,465), Sparks et al (USPN 4,952,402) and Medford et al (USPN 5,380,747) all in view of Chen et al (USPN 6,180,606). The claims are drawn to a device, which delivers vasodilating agents where the formulation comprises the agents and a biocompatible carrier. The carrier is biodegradable, and is recited to be methylcellulose or equine collagen. The agents are selected from well-known vasodilators such as nitroglycerine, and verapamil. Claims 13 – 23 are drawn to a method of delivering vasodilating agents using the device of the agent.

As discussed above Kwiatek, Kigasawa, Sparks, and Medford anticipate many essential elements of the claimed invention. The references disclose devices that deliver vasodilators along with biocompatible carriers. The references do not however disclose the concentrations of

the particular vasodilators present in the carriers. The references collectively disclose methylcellulose and collagen as possible carriers of vasodilators (collagen in the case of Medford). Though suggested by Medford the reference, do not disclose specifically equine collagen as a carrier, merely that collagen can be used. The references also do not disclose the disposal of the devices.

With regard to the concentrations of the vasodilating agents in the carrier, the references all disclose the general combination of a topical formulation of a vasodilating agent with a biocompatible carrier. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various topical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With regard to the recitation of the equine collagen, it is the position of the examiner that such a limitation is merely the selection of an equivalent species, which would be obvious to one of ordinary skill in the art. As seen in Chen, which discloses the use of collagen as a biocompatible carrier composition, equine, human, bovine, and porcine or ovine collagen can be used and interchanged for the purposes of carrying an active agent (Abstract; Examples, claim 40). It is the position of the examiner that due to the knowledge in the art as to the equivalency

of these collagen sources for the purposes of active agent carrying, the selection of equine collagen does not impart patentability to the invention barring a showing of criticality to that particular source along with unexpected results of the choice.

With this in mind a skilled artisan would have been motivated to combine the teachings and suggestions in the art. A skilled artisan would have first been motivated to modify the topical formulation of Kwiatek, Kigasawa, Sparks, and Medford, through routine experimentation to determine the optimal concentration of vasodilating agents represented in the carrier compositions, in order to maximize the delivery of the agents. Following the knowledge of Chen and under the suggestion of Medford and Kwiatek, a skilled artisan would have been motivated to select the best collagen source in order to achieve optimal biocompatibility. A skilled artisan would have been able to determine the best mode of disposal of the device as well. A skilled artisan also would have been able to determine the optimal duration of exposure to the device, through routine experimentation in order to maximize the effectiveness of the agents, and dilate the blood vessels completely. It would have been obvious to apply the knowledge of Chen to any of the other references and to include collagen from other sources to act as a biocompatible, biodegradable carrier composition. It would have been obvious to one of ordinary skill in the art, at the time of the invention, to combine the teachings, knowledge and suggestions in the art, with an expected result of a method for delivering vasodilating agents to a patient along with a device, which optimizes the effectiveness of the agents.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

M. Young
December 14, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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